REMARKS

The March 11, 2003 Official Action has been carefully considered. In view of the amendments submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three months was set in the March 11, 2003 Official Action. Accordingly, the initial response period expired June 11, 2003. A petition for a one-month extension of the response period is presented with this Amendment and Request for Reconsideration Under 37 C.F.R. §1.111, which is being filed within the one-month extension period.

Applicants once again take exception to the restriction requirement in this case, which was maintained and made final in the March 11, 2003 Official Action. As applied to the allegedly distinct inventions of Group III (i.e., Claims 3, 53-58 and 63-66) and Group IV (i.e., Claims 59-62), this requirement contravenes well-established U.S. Patent and Trademark Office practice regarding the proper implementation of the PCT's unity of invention standards, and, as such, is plainly unjustified.

The Examiner attempts to defend this requirement by reiterating the flawed rationale of paragraph 6 of the October 10, 2002 Official Action. In that Official Action, the Examiner contended that "[n]one of the inventions of Groups I-III share the same or similar technical feature of invention in Group IV, an isolated nucleotide sequence". In the present Office Action, the Examiner asserts that "a 'correspondence' between nucleic acids and polypeptide...is not a special technical feature shared between the two groups". The Examiner's position in this regard

is manifestly untenable.

As stated in 1893.03(d) of the M.P.E.P.:

> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.
>
> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.... Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P.

Example 17 of Annex B Part 2 of the above cited Administrative Instructions reads as follows:

> ....Example 17
> Claim 1: Protein X.
> Claim 2: DNA sequence encoding protein X.
>
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Thus, a protein and the DNA sequence encoding it exhibit "corresponding special technical features" and, therefore, satisfy the PCT's unity of inventive requirement.

Accordingly, in the present case, Claims 3, 53-58 and 63-68 , on the one hand, and Claims 59-62 on the other hand, cannot properly be characterized as lacking unity of invention. It is noteworthy in this regard that there was no lack of unity objection during the international stage of this application. Rather, the subject matter of all of the original claims was considered to be a single inventive concept. That being the case, the present requirement directly contravenes the unity of invention standard established under the PCT.

As the restriction requirement set forth in this case fails to comply with established United States Patent and Trademark Office (PTO) practice, it is respectfully submitted that this requirement should be reconsidered and withdrawn, at least insofar as Groups III and IV are concerned.

Established procedures for examination of U.S. national stage applications filed under the PCT cannot simply be disregarded in favor of normal restriction practice, as the latter is inapplicable in this case. Considerations such as the PTO's classification system and Examiner workload have no place in making unity of invention determinations. In the event the Examiner maintains the position that the subject matter of Groups III and IV is patentably distinct, it is respectfully requested that specific citation of relevant authority be provided that is believed to warrant such action.

In the March 11, 2003 Official Action, the specification is objected to because of the omission of sequence identification numbers that comply with PTO Rules of Practice, and correction is required. In addition, an amendment is requested that would identify the present application as a §371 application and claim

priority to GB 9825418.8 filed November 19, 1998. It is noted in this connection that applicants' claim for priority was duly made during International proceedings, as well as in the executed declaration filed in the present application. Nothing further is required to establish a claim of foreign priority under 35 U.S.C. §119. Thus, the requested specification amendment is considered superfluous.

Certain claims were also found objectionable in the March 11, 2003 Official Action. Specifically, Claim 3 was characterized as improper in view of abbreviations "X." and "B." Claims 64 and 66 were deemed objectionable because they omit sequence identification numbers in compliance with the PTO Rules of Practice.

Turning to the substantive aspects of the March 11, 2003 Official Action, Claims 3, 53-58 and 63-66 stand rejected under 35 U.S.C. §112, first paragraph, based on allegedly insufficient enablement. In support of this rejection, the Examiner contends that the enablement provided in the specification is not commensurate with the scope of claims that Applicants are pursuing in this application. The Examiner acknowledges, however, that the specification is enabling for a pesticidal agent obtained from two strains of *Xenorhabdus bovenii*, H31 and I73, and having activity against *Pieris brassicae*, *Plutella xylostella*, *Phaedon cochleariae*and *Myzus persicae*. The Examiner further asserts in this regard that the specification is not enabling for the polypeptide of Claim 64 which is referred to as having "70% or more sequence identity" with SEQ ID NOS: 1-4. According to the Examiner, undue experimentation would be required of those having ordinary skill in the art in order to

practice the invention as originally claimed, because the present specification allegedly fails to satisfy the so-called "Wands" factors.

Claims 3, 53-58 and 63-66 have been separately rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to provide or present (i) an adequate written description of the invention, (ii) an enabling disclosure, and (iii) the best mode contemplated by applicants for carrying out the invention, in the absence of evidence showing that the claimed biological materials are either known or readily available to the public or were duly deposited with a recognized depository. The Examiner indicates that a sworn statement by a competent individual or a statement in appropriate form by an attorney of record, to the effect that the biological materials in question have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability of the deposited materials to the public will be irrevocably removed upon grant of a patent, would satisfy the deposit requirements.

Claims 57, 58 and 63-66 have been rejected under 35 U.S.C. §112, second paragraph, for allegedly failing to particularly point out the subject matter which Applicants regard as the invention. Specifically, the Examiner regards the recitation of "H toxin or I toxin" (in Claims 57 and 58) "insecticidal toxin" and "bacterial nematode-symbiont" (in Claim 65) and "derivative" (in Claim 66) to be indefinite for the reasons stated at pages 6-7 of the March 11, 2003 Official Action.

Claims 3, 53-58 and 63-66 have also been rejected under 35 U.S.C. §102(b) as allegedly anticipated by, or in the alternative, under 35 U.S.C. §103(a) as allegedly obvious in view

of Jarrett et al. (WO 98/08388), considered in view of International J. Systematic Bacteriology (Vol. 43, pp. 864-65 (1993)) (hereinafter "the IJSB publication") and Ensign et al. (WO 98/50427). It is the Examiner's position that Jarrett et al. inherently discloses insecticidal toxins from *X.bovienii* having pesticidal activity against at least two insect orders and synergistic pesticidal activity with *B.thuringensis* cells. The Examiner further contends in this regard that even if Jarrett et al. does not inherently anticipate the present invention, it nevertheless renders the invention obvious because Jarrett et al. purportedly discloses members of the same genus and species and the agent obtained therefrom through the same steps and having the same functional properties toward the members of the same insect orders as called for in applicants' claims.

The foregoing objections and rejections constitute all of the grounds set forth in the March 11, 2003 Official Action for refusing the present application.

In accordance with the present amendment, Claim 3 has been amended to specify H31 or I73 as the, X.bovienii strain, as well as the insect species for which data is provided in the examples. The abbreviations (X. and B.) have been omitted from Claim 3 as currently amended.

The dependency of Claim 63 has been amended so that it now depends from Claim 55, rather than Claim 58.

Claim 64 has been amended so as to be independent, rather than dependent from Claim 3. Additionally, Claim 64 now recites that the agent is a polypeptide encoded by a nucleic acid comprising a homologous variant of any one of the sequences of the invention, having about 70% or more sequence identity

therewith, and is an insecticidal toxin. Accordingly, Claim 64 as currently amended, provides antecedent basis for the recitation of "insecticidal toxin" in Claim 65. The recitation of "bacterial nematode-symbiont" in Claim 65 is a further limitation as to the source of the insecticidal toxin, and as such, does not require antecedent basis in Claim 64. Appropriate SEQ ID NOS are recited in Claims 60, 62, 63, 64 and 66. This amendment, together with that of Claim 3 noted above, is believed to overcome the claims objections in the March 11, 2003 Official Action.

Claims 53-56 are unchanged.

Claims 57 and 58 have been cancelled, thus rendering moot the 35 U.S.C. §112, second paragraph, rejection of those claims. Applicants' cancellation of Claims 57 and 58 is without prejudice to their right to file a continuing patent application, as provided under 35 U.S.C. §120, with respect to the subject matter of those claims.

Also in accordance with the present amendment, appropriate SEQ ID NOS have been inserted at pages 5 and 6 of the specification. Accordingly, the objection to the specification set forth in the March 11, 2003 Official Action is believed to be overcome.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

For the reasons set forth below, Applicants respectfully submit that the rejections of Claims 3, 53-58 and 63-66, based variously on 35 U.S.C. §112, first and second paragraph, and 35 U.S.C. §§102/103, as set forth in the March 11, 2003 Official Action, either lack merit or cannot be maintained in view of the

present amendments. These grounds of rejection are, therefore, respectfully traversed.

A. CLAIMS 3, 53-58 AND 63-66 FULLY COMPLY WITH THE ENABLEMENT REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH

1. The Enablement Provided By The Specification Is Commensurate With The Scope Of Applicants' Claims As Now Amended.

The specification is clearly enabling for agents from the two X. bovienii, strains now recited in Claim 3 and which have activity against one or more of the insect species recited therein. Indeed, paragraph 12 of the March 11, 2003 Official Action acknowledges that the subject matter of Claim 3, as currently amended, is sufficiently enabled by the present specification.

As for the recitation of "70% or more sequence identity" in Claim 64, it is respectfully submitted that the present specification is enabling for the subject matter of Claim 64 as currently amended. The meaning for the terminology in question is set forth in the present specification at page 8, line 15 through page 9, line 25. This description is completely consistent with the knowledge and understanding of those skilled in the art regarding the concept of nucleic acid sequence identity. It is certainly not an undue burden for those skilled in the field of the field of the present invention to determine whether a nucleic acid comprises a nucleotide sequence having 70% or more sequence identity with one or more of the recited nucleotide sequences and consequently encodes an agent of the invention having the required insecticidal activity, which activity can be ascertained by routine testing.

Applicants also take exception to the Examiner's

conclusionary recitation of the Wands factors as supporting the position that undue experimentation is required to practice this invention. The presently amended claims cannot be considered unduly broad. Moreover, the level of skill in the field of this invention is quite high. The state of the art is well-developed and the present specification provides working examples and guidance which are more than sufficient to practice the full scope of the claimed invention. Although some experimentation may be necessary in carrying out the present invention, given the unpredictability in recombinant DNA technology, the amount of experimentation involved cannot reasonably be considered excessive or undue in light of the disclosure provided by applicants herein. Therefore, when all of the Wands factors are duly considered, it is beyond question that the claimed invention is fully enabled by the present specification.

For all of the above reasons, the 35 U.S.C. §112, first paragraph rejection set forth in Section 12 of the March 11, 2003 Official Action is untenable and should be withdrawn.

2. The 35 U.S.C. §112, First Paragraph, Rejection Of Claims 3, 53-58 and 63-66 Set Forth In Section 13 Of The March 11, 2003 Official Action Is Overcome By The Declaration Of Deposited Materials Submitted Herewith.

The Declaration of Deposited Materials (Declaration) submitted herewith complies with the requirements set out in Section 13 of the March 11, 2003 Official Action by establishing that the deposit was made under the terms of the Budapest Treaty and that the deposited strain will be made available to the public irrevocably and without restriction or condition upon issuance of a patent on the present application. It is noted in

this connection that the present specification refers to the deposited materials by Accession Number and further identifies the name and address of the depository. This information appears at page 3, lines 5-10 of the present specification. The Declarant, Peter Little, has made this declaration in his capacity as Commercial Manager of Horticulture Research International (HRI), the applicants' assignee. Evidence of the ownership rights of HRI is provided by the assignment from the Applicants to HRI which is attached to the Declaration.

In view of the Declaration submitted herewith, the 35 U.S.C. §112, first paragraph rejection set forth in Section 13 of the March 11, 2003 Official Action should be withdrawn.

It should be noted that the Declaration of Deposited Materials submitted herewith is unexecuted. The Declaration has been forwarded to the declarant for execution. The executed Declaration will be filed promptly upon receipt by the undersigned.

B. CLAIM 66 SATISFIES THE DEFINITENESS REQUIREMENT OF 35 U.S.C. §112, SECOND PARAGRAPH.

The appropriate procedure for determining compliance with the definiteness requirement of 35 U.S.C. §112, second paragraph, was stated In re Morris, 44 USPQ.2d, 1023, 1027 (Fed. Cir. 1997), as follows:

> [A]s an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the Applicants' specification.

See also, *Ex parte* Cole, 223 USPQ 94 (Bd. Apps. 1983). (Claims are addressed to the person of average skill in the particular art. Compliance with §112 must be adjudged from that perspective, not in a vacuum.)

Furthermore, it has long been held that the initial burden of establishing a failure to comply with §112, second paragraph, rests upon the Examiner. In rejecting a claim for alleged indefiniteness, therefore, it is incumbent upon the Examiner to establish that one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claim when read in light of the supporting specification. *Ex parte* Cordova, 10 USPQ.2d 1949, 1952 (PTO BPAI 1998).

When the appropriate procedure is followed in assessing the claim terminology at issue, in accordance with the above-cited authorities, it is beyond question that Applicants have satisfied the definiteness requirement of §112, second paragraph, with respect to the term "derivative" in Claim 66.

The term "derivative" as recited in Claim 66 cannot reasonably be considered unclear, confusing or indefinite when it is properly considered in context. Claim 66 further qualifies what is meant by "derivative" with the recitation "by way of addition, insertion, deletion or substitution of one or more nucleotides". Moreover, the recited "one or more nucleotides" refers to the nucleotide sequences identified as SEQ ID NOS: 1-4. Thus, the term in question does not refer to any derivative, but to derivatives which are obtainable from specifically recited sequences by way of addition, insertion, deletion or substitution and which have pesticidal activity, given that Claim 66 ultimately depends from Claim 3.

Considering also the "enlightenment...that may be afforded by the written description contained in the applicants' specification", per In re Morris, supra, the challenged claim recitation cannot reasonably be considered indefinite. Thus, the present specification at page 9, line 27 through page 11, line 15, clearly explains what is meant by the term "derivative". This disclosure leaves no doubt that the term "derivative", as recited in Claim 66, is both clear and definite.

In summary, applicants' position with respect to the rejection of Claim 66 based on 35 U.S.C §112, second paragraph, is that any person skilled in the art, having applicants' disclosure and claims before him or her, would be apprised to a reasonable degree of certainty as to the exact subject matter encompassed within Claim 66. Nothing more is required under 35 U.S.C §112, second paragraph.

For all of the foregoing reasons, it is clear that the USPTO has failed to satisfy its burden of proof with respect to the §112, second paragraph, rejection of Claim 66 as set forth in the March 11, 2003 Official Action. Accordingly, this ground of rejection is improper and should be withdrawn.

C. THE PRIOR ART REJECTION OF CLAIMS 3, 53-58 AND 63-66, BASED ALTERNATIVELY UNDER 35 U.S.C. §102(b) OR §103(a) IN VIEW OF JARRETT ET AL. CONSIDERED IN LIGHT OF THE IJSB PUBLICATION AND ENSIGN ET AL. CANNOT BE MAINTAINED.

Rejections under 35 U.S.C. §102 are proper only when the claimed subject matter is identically disclosed or described in the allegedly anticipating reference. In re Arkley, 172 USPQ 524 (CCPA 1972). Applying this rule of law to the present case, the 35 U.S.C. §102(b) rejection of Claims 3, 53-58 and 63-66 is

plainly improper because Jarrett et al. fails to identically disclose the subject matter of the rejected claims, either expressly or inherently.

The Examples in Jarrett et al. concern *X. nematophilus*. The use of 16s rRNA analysis has confirmed that the strains claimed in the present application are *X. bovienii* and are quite distinct from *X. nematophilus*, and indeed this is clearly shown in the dendogram of Fig 1. The fact that they share certain characteristics does not mean that the strains are inherently the same, nor does it imply that any observations made in Jarrett et al. about *X. nematophilus* would be applicable to *X. bovienii*.

Notwithstanding the Examiner's assertion to the contrary, the agents of the present invention are not only obtained from a different source relative to those of Jarrett et al. (i.e. from *X. bovienii*) but they also have a different host-range. The agents of the present invention are active against coleopteran pest species such as *Phaedon* and homopteran pest species such as *Myzus*. Jarrett et al. does not disclose agents with activity against either of these, only against lepidopteran and dipteran pest species (page 2, final paragraph).

Inasmuch as Jarrett et al., considered in light of the IJSB publication and Ensign et al., fails to identically disclose or describe the subject matter of Claims 3, 53-58 and 63-66, the §102(b) rejection of Claims 3, 53-58 and 63-66 based on those references is clearly improper and should be withdrawn.

As for the alternate basis for rejection under §103(a), the Examiner appears to allege that the *X. nematophilus* agents disclosed in Jarrett et al. would be predictive of the properties of the *X. bovienii* agents of the present invention, rendering the

later obvious.

Here again, the fact that *X. nematophilus* and *X. bovienii* species share certain characteristics does not imply that any observations made in Jarrett et al. about *X. nematophilus* (eg. about pesticidal agents thus obtained) would apply to *X. bovienii*.

In fact, as indicated above, the agents *X. bovienii* of the present invention are active against a <u>different</u> range of pest species to those from *X. nematophilus* disclosed in Jarrett et al.

Thus, while the skilled person <u>may</u> have considered the possibility that other *Xenorhabdus* species may yield pesticidal agents, the skilled person <u>would not</u> have been led by Jarrett et al. to arrive at the present invention, which provides agents which expand the range of pests which can be controlled.

Therefore, it would not have been obvious to the ordinarily skilled person that *X. bovienii* species would have agents having the properties of agents from *X. nematophilus*, which is borne out by the fact that *X. bovienii* agents have activity against a <u>different</u> range of pest species.

The Examiner also appears to allege that the agents disclosed in Ensign et al. share properties with those of Jarrett et al., thus rendering obvious the *X. bovienii* agents of the present invention.

However, while Ensign et al. concerns itself with a wide variety of *Xenorhabdus* strains, (i) it does not identify any of those strains as *X. bovienii,* (ii) it does not give any sequence which can be compared with the presently claimed sequences, (iii) it does not disclose the same activities which are demonstrated for the present invention (see e.g. page 29 of the present

application, which discusses *Myzus persicae*, a homopteran pest species). In particular, since no activity against *Myzus* was demonstrated for the agents of Ensign et al., *prima facie* there is no reason to assume that they are related to, or when considered in conjunction with Jarrett et al. would suggest the specific class of the present invention.

In light of the above-noted differences, it cannot reasonably be maintained that the combined disclosures of Jarrett et al., the IJSB publication and Ensign et al. render the subject matter of the present claims obvious.

There is no dispute that a few of the characteristics of the presently claimed toxins (e.g. molecular weights, toxicity to individual insect species) may be shared with the prior art. Such limited similarities as exist, however, certainly do not warrant the conclusion that the present invention, as defined by the combination of <u>all</u> the technical features in the claims, would have been obvious over that art when there are also clear differences between them (Jarrett et al. and the IJSB publication) or when the prior art is simply too vague to be able to make a properly reasoned or justified comparison (Ensign et al.).

It is noted in this connection that the prior art rejections in the March 11, 2003 Official Action appear to reiterate positions taken by the European Patent Office in its capacity as International Preliminary Examining Authority during International proceedings, in applicants' PCT application. When the EPO took up the corresponding EPO regional stage application for examination, however, claims that are substantially the same as those pending in the present application were accepted without

any of the objections raised in the International Preliminary Examination Report being repeated. The European equivalent of the present application is European Patent No. 1130970. The grant of the corresponding European patent constitutes additional evidence that the present claims are patentably distinguishable from Jarrett et al., considered in light of the IJSB publication and Ensign et al.

In view of the present amendments, the Declaration of Deposited Materials submitted herewith and the foregoing remarks, it is respectfully requested that the objections and rejections set forth in the March 11, 2003 Official Action be withdrawn and that this application be passed to issue and such action is earnestly solicited.

Respectfully submitted,

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Enclosure: Declaration of Deposited Materials